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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/652,846	08/29/2003	Timothy J. O'Brien	D6020CIP4	5440

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EXAMINER	
HUYNH, PHUONG N	

ART UNIT	PAPER NUMBER
1644	

DATE MAILED: 09/12/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/652,846	O'BRIEN ET AL.	
	Examiner	Art Unit	
	Phuong Huynh	1644	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *One* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *8/29/03*.

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-66* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-66* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

I. Claims 1-66 are pending.

Election/Restrictions

II. Restriction to one of the following inventions is required under 35 U.S.C. 121:

1. Claims 1-8 and 52-55, drawn to an **isolated DNA** encoding a Tumor Antigen Derived Gene-14 (TADG-14) that has amino acid sequence shown in SEQ ID NO: 7 and an isolated DNA encoding a **TADG-14 protein variant** that has amino acid sequence of SEQ ID NO: 75**, vector and host cell**, classified in Class 536, subclass 23.5; Class 435, subclass 252.3, 320.1.

2. Claims 9-10, 45-47, and 56, drawn to **isolated and purified TADG-14 protein**, an immunogenic composition comprising an immunogenic fragment of TADG-14 protein of SEQ ID NO: 7 and a TADG-14 variant that has the amino acid sequence of SEQ ID NO: 75 or a fragment thereof, classified in Class 530, subclass 300.

3. Claim 11-14 and 57-58, drawn to a **method of detecting TADG-14 mRNA or variant thereof** comprising the steps of contacting a sample with a **probe** specific for TADG-14 or TADG-14 variant, classified in Class 435, subclass 6.

4. Claims 15-16, 48-49 and 59, drawn to a **kit for detecting TADG-14 mRNA** comprising an **oligonucleotide probe** specific for TADG-14 wherein said probe comprises sequence complementary to SEQ ID NO: 6, an oligonucleotide having the sequence of SEQ ID NO: 72, a composition comprising said oligonucleotide having the sequence of SEQ ID NO: 72, and a kit for detecting TADG-14 variant mRNA comprising an oligonucleotide probe specific for TADG-14 variant mRNA wherein said probe comprises a sequence complementary to the DNA that encodes the amino acid sequence of SEQ ID NO: 75, classified in Class 536, subclass 23.5; Class 436, subclass 548.

5. Claims 17-20 and 60-61, drawn to a **method of detecting TADG-14 protein and a TADG-14 variant protein** comprising the steps of contacting a sample with **an antibody** specific for TADG-14 or an antibody specific for TADG-14 variant or binding fragment thereof, classified in Class 435, subclass 7.1.

6. Claims 21-23 and 62-63, drawn to a **kit for detecting TADG-14 and TADG-14 variant protein** comprising an **antibody** or a binding fragment thereof specific for TADG-14 and an antibody or a binding fragment thereof specific for TADG-14 variant protein, classified in Class 530, subclass 387.1; Class 436, subclass 548.

7. Claim 24, drawn to **a method of screening for compounds that inhibit protease activity of TADG-14**, classified in Class 435, subclass 7.93.

8. Claim 25, drawn to **a method of inhibiting expression of TADG-14 in a cell comprising the step of introducing an anti-sense DNA vector specific for TADG-14 into a cell**, classified in Class 536, subclass 24.5.

9. Claim 26, drawn to **a method of inhibiting a TADG-14 protein in a cell comprising the step of introducing an antibody or binding fragment thereof specific for TADG-14 protein in said cell**, classified in Class 435, subclass 7.21.

10. Claims 27-30, drawn to a **method of targeted therapy** to an individual comprising the steps of administering to an individual a **compound having a targeting moiety and a therapeutic moiety** wherein said targeting moiety is specific for TADG-14, classified in Class 424, subclass 178.1.

11. Claims 33 and 66, drawn to **a method of diagnosing cancer** in an individual comprising the steps of obtaining a biological sample from an individual and detecting TADG-14 or TADG-14 variant having the amino acid sequence of SEQ ID NO: 75, in said sample by means of **Northern blot**, classified in Class 435, subclass 178.1.

12. Claims 33, and 66, drawn to **a method of diagnosing cancer** in an individual comprising the steps of obtaining a biological sample from an individual and detecting TADG-14 or TADG-14 variant having the amino acid sequence of SEQ ID NO: 75 in said sample by means of **Western blot, dot blot, ELISA sandwich assay, radioimmunoassay, flow cytometry**, classified in Class 435, subclass 7.1.

13. Claims 33 and 66, drawn to **a method of diagnosing cancer** in an individual comprising the steps of obtaining a biological sample from an individual and detecting TADG-14 or TADG-14 variant having the amino acid sequence of SEQ ID NO: 75 in said sample by means of **PCR**, classified in Class 435, subclass 178.1.

14. Claims 33 and 66, drawn to **a method of diagnosing cancer** in an individual comprising the steps of obtaining a biological sample from an individual and detecting TADG-14 or TADG-14 variant having the amino acid sequence of SEQ ID NO: 75 in said sample by means of **DNA array chips**, classified in Class 435, subclass 178.1.

15. Claims 35-38, drawn to **a method of vaccinating** an individual against TADG-14 protein comprising the step of inoculating an individual with a TADG-14 protein or fragment thereof that lacks TADG-14 protease activity, classified in Class 424, subclass 184.1.

16. Claims 39-44, drawn to **a method of producing activated immune cells** directed toward TADG-14, classified in Class 424, subclass 184.1.

17. Claims 50-51, drawn to **a method of treating a neoplastic state** in an individual comprising the step of administering to said individual an effective dose of the composition comprising the oligonucleotide having a sequence of SEQ ID NO: 72, classified in Class 514, subclass 44.

Linking claims 31-32, 34 and 64-65 will be examined along with Groups 11-14 if any one of said Groups is elected.

Claims 31-32, 34 and 64-65 link inventions 11-14. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 31-32, 34 and 64-65.

Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

The inventions are distinct, each from the other because:
Inventions of Groups 1, 2, 4 and 6 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case, the products such as DNA, protein, oligonucleotide, and antibody as claimed differ with respect to its structure, biochemical properties and function. Therefore, they are patentably distinct.

Inventions of Groups 3, 5 and 7-17 are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01).
The instant specification does not disclose that these methods would be used together. The methods of groups 3, 5 and 7-17 as claimed are all unrelated, as they comprise distinct method steps, utilize different product and resulting in different endpoint. Therefore, they are patentably distinct.

Inventions of Group 4 and Groups (3, 13 and 14) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the oligonucleotide as claimed can be use for

detecting TADG-14 mRNA as opposed to its use in screening assays or diagnosing cancer. Therefore, they are patentably distinct.

Inventions of Group 6 and Groups (5, 9 and 12) are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the antibody as claimed can be use for detecting TADG-14 as opposed to its use in inhibiting TADG-14 protein in a cell. Therefore, they are patentably distinct.

III. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and/or recognized divergent subject matter. Further, even though in some cases the classification is shared, a different field of search would be required based upon the structurally distinct products recited and the various methods comprising the distinct method steps. A prior art search also requires a literature search. It is an undue burden for the examiner to search more than one invention. Therefore restriction for examination purposes as indicated is proper.

IV. Applicant is advised that the response to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed.

V. The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claims are subsequently found allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be considered for rejoinder. All claims directed a nonelected process invention must require all the limitations of an allowable product claim for that process invention to be rejoined.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until all claims to the elected product claim are found allowable, an otherwise

proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See MPEP § 821.04(b). Additionally, in order to retain the right to rejoinder in accordance with the above policy, applicant is advised that the process claims should be amended during prosecution to require the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.** Further, note that the prohibition against double patenting rejections of 35 U.S.C. 121 does not apply where the restriction requirement is withdrawn by the examiner before the patent issues. See MPEP § 804.01.

VI. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Phuong Huynh "NEON" whose telephone number is (571) 272-0846. The examiner can normally be reached Monday through Friday from 9:00 am to 5:30 p.m. A message may be left on the examiner's voice mail service. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached on (571) 272-0841. The IFW official Fax number is (703) 872-9306.

VII. Any information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

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